HENRY ROYCE INSTITUTE

MATERIALS FOR BIOELECTRONICS IN HEALTHCARE

STRATEGY AND ACTION PLAN SUMMARY

THIS SUMMARY

This document has been commissioned by the Henry Royce Institute and prepared by CPI, ScotChem and Urban Foresight in collaboration with a team of global expertise across industry, government and academia. It presents the findings from a strategy development process completed between February and July 2024.

The full report can be found on Royce's website at: royce.ac.uk/collaborate/roadmapping-landscaping/materials-for-bioelectronics-in-healthcare/

All statements and recommendations in this document have been developed in a research setting and are not current policy of the UK Government, UKRI, Royce, or other named public bodies. Please contact Urban Foresight if you have any questions about this report.

This strategy was developed with Royce's Bioelectronics Working Group: Kim Chaffin PhD PE, Vice President Corporate Technologist for Medtronic, Professor Róisín M Owens, Department of Chemical Engineering and Biotechnology at the University of Cambridge, and Lisa Hearty, the Research Business Development Manager for Biomedical Materials at Royce.

A complete list of contributing authors and acknowledgments is provided in the full report.

WHAT IS BIOELECTRONICS?

Bioelectronics is the electronic monitoring and control of biological systems for applications in medicine, agriculture, industry, and the environment.

In healthcare, these are electronic systems that directly interface with biological systems (in vivo or in vitro) for the purposes of prevention, diagnosis, monitoring, treatment and curing of disease, for patient rehabilitation, and for improving health in general.

Pacemakers, blood glucose monitors and cochlear implants are examples of established bioelectronic healthcare solutions, as are a wide range of emerging solutions in neurotechnology and regenerative medicine.

THE BIOELECTRONICS MARKET

The estimated global market size for bioelectronics was between £7.8 billion and £17.6 billion in 2024. This is projected to reach between £16.2 billion and £27.9 billion by 2030.

The UK has an active research sector in bioelectronics, producing around 11% of scientific papers published globally in the sector and 2.64% of all bioelectronics patent applications – the highest of any European country.

Materials are the basis for innovation in bioelectronics. 1 in 4 scientific papers on bioelectronics are related to materials science, and "materials" is the most frequently used word in bioelectronics patent abstracts.

Materials will play a key role in supplying safe and responsible – but disruptive – bioelectronic healthcare solutions.

If the UK can successfully translate its materials for bioelectronics research into commercial healthcare solutions, then it will capture a significant proportion of this high-value global market and establish itself as a leader in this research area worldwide.

THIS STRATEGY

The Henry Royce Institute is the UK's hub for advanced materials. Royce has recognised the importance of materials innovation to the emerging bioelectronics in healthcare sector. The institute has created this strategy to define the sector's demand for materials solutions and the actions to take to meet it.

This strategy's development saw over 60 researchers, innovators, funders, policy makers and clinicians share their experiences and views on materials innovation for bioelectronics in healthcare. This included an online survey and one-to-one interviews, which were followed by a consultation with an additional 70 researchers attending the Cambridge Bioelectronics Symposium.

This engagement developed new data on the activity of bioelectronics in healthcare in the UK, materials in use, and the material properties required by the sector in the future. This primary research produced a roadmap of materials, with three Grand Challenges to be pursued by researchers and innovators.

Insights into the strengths of this community and the challenges they face in progressing a new material solution for bioelectronics in healthcare were also captured. These have directly informed recommended action plans for accelerating materials research in this sector in the UK.

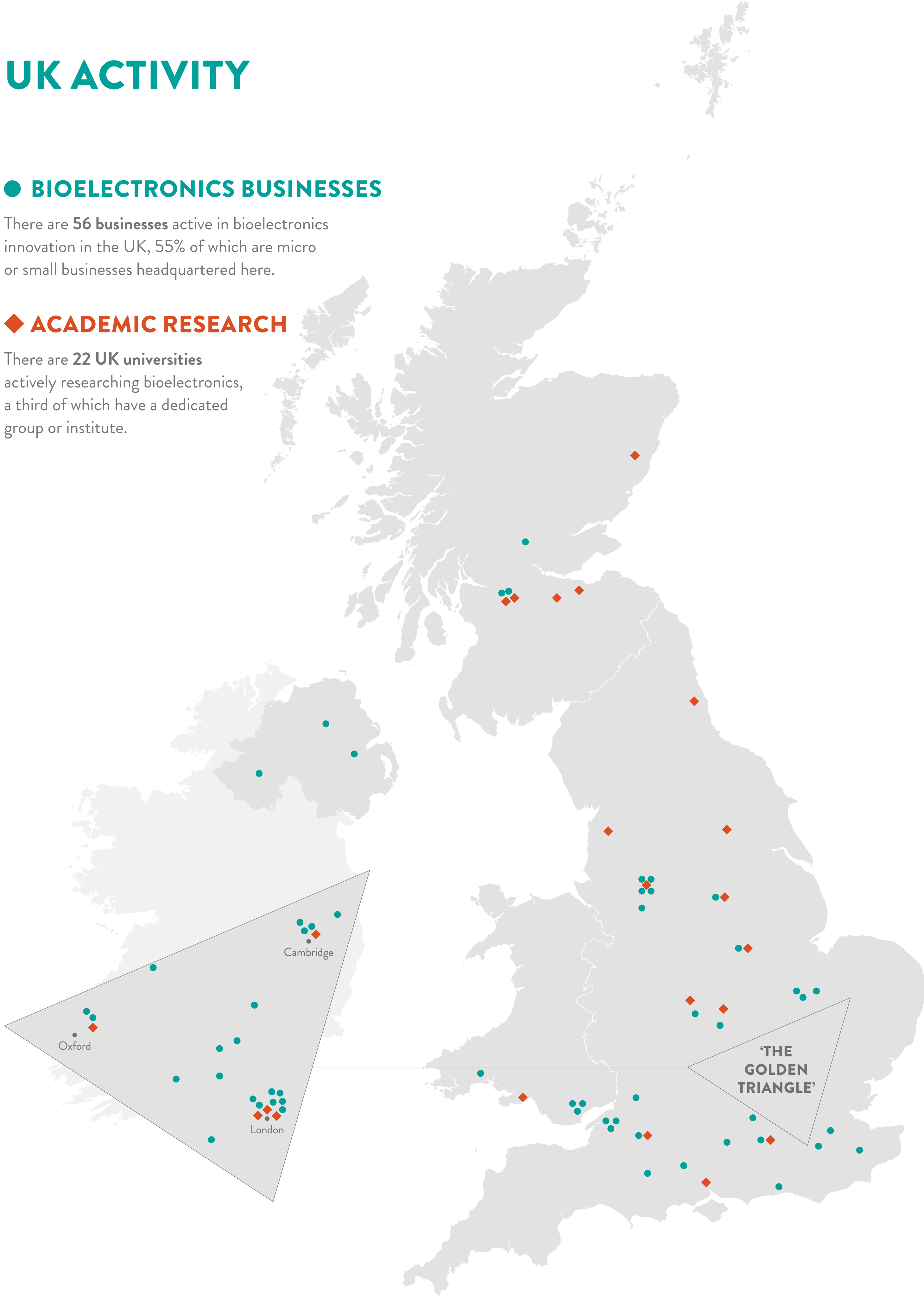
UK ACTIVITY

● BIOELECTRONICS BUSINESSES

There are **56 businesses** active in bioelectronics innovation in the UK, 55% of which are micro or small businesses headquartered here.

◆ ACADEMIC RESEARCH

There are **22 UK universities** actively researching bioelectronics, a third of which have a dedicated group or institute.



BIOELECTRONIC MATERIALS FOR HEALTHCARE ROADMAP

There are a diverse range of applications for which bioelectronic materials are being used in healthcare and there are a wide range of different materials either in use or in development.

The main materials currently in use in industrial bioelectronic products are those which are already known to have good biocompatibility and long-term stability when implanted or connected to the body. For example, titanium, iridium oxide, or some polymers like polyurethane.

For devices which contact the body externally, such as wearable devices or biosensors, the conducting polymer PEDOT:PSS is frequently used.

In terms of future materials demand, rather than mapping specific materials, this roadmap maps the properties of materials that are likely to have the highest impact.

Impact was deemed higher if the material property was mentioned by multiple respondents to the survey, or if the material property was cited in the context of a product or application development beyond the laboratory.

In the near term, materials with good electrical properties as well as good biocompatibility are likely to have the highest impact.

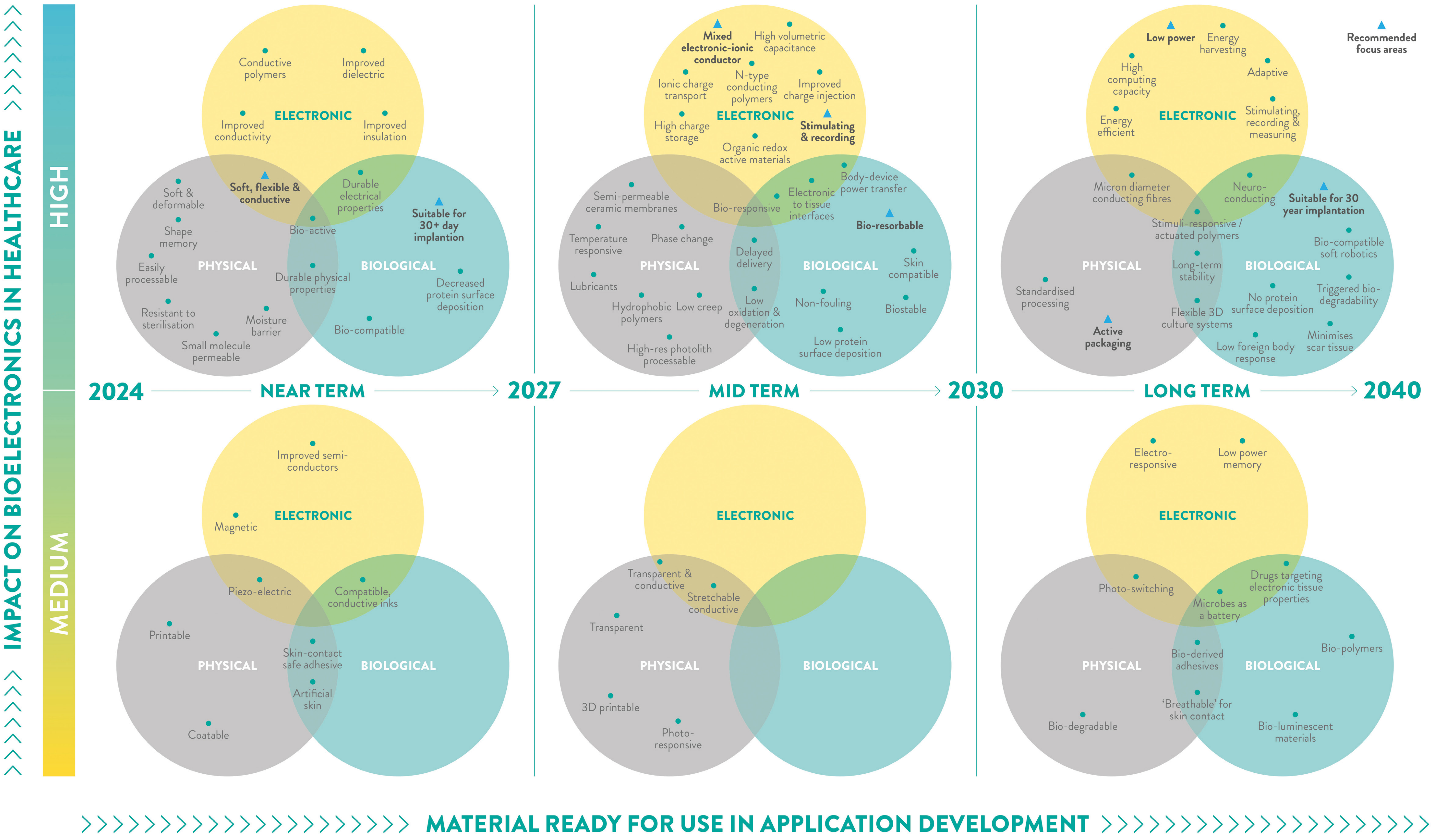
In the future, higher impacts will come from materials which have combinations of desirable electronic, physical and biological properties. For example, stretchable, flexible and conductive biocompatible materials. The ease of processing of these materials will impact their uptake.

Looking out further into the future, materials which are active or "smart" in their response to stimuli will be important, along with materials which can withstand degradation in the body for extended periods of time – in the region of 30 years or more – and bioresorbable materials that dissolve in the body at the end of their operating lifespan.

Only materials that offer transformative properties or a significant step change in performance are likely to be progressed into longer term studies due to the high cost and significant time required to demonstrate their suitability for bioelectronics.

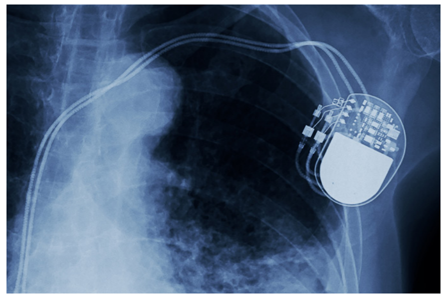
MATERIALS FOR BIOELECTRONICS ROADMAP

The physical, electronic and biological material properties required by bioelectronic solutions into the future.



MATERIALS FOR BIOELECTRONICS IN HEALTHCARE GRAND CHALLENGES

Three Grand Challenges have been distilled from the roadmap, providing focal points for the development of advanced materials that meet the needs of the bioelectronics in healthcare sector.

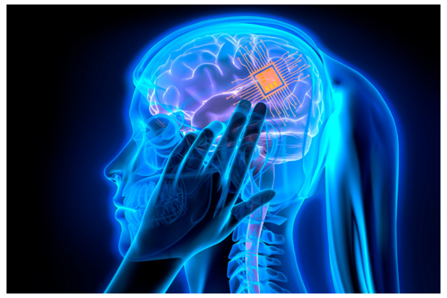


1. Long-term (>10ys) implantable materials

Materials that can withstand implantation for very long periods of time (many years) but maintain all their required functions (i.e. mechanical strength, permeability). Decreasing or moderating the foreign body response (through drug release, morphology and material properties) and decreasing protein deposition onto the surface are potential solutions.

2. Materials with ideal electrical properties

Electrically conducting materials with good biocompatibility and mechanical properties similar to tissue, making them ideally suited to interfacing electronics with the body for long periods of time. These materials should allow good charge injection across a wide range of frequencies. Materials with mixed electronic and ionic conduction, for example, have improved biocompatibility compared to metals and can perform better when interacting with ion channels and signalling pathways.



3. Materials which improve sensor performance in vivo

In vivo sensors suffer from biofouling, caused by the accumulation of proteins or cells on the sensing surface or inflammatory response of the body to the sensor. Biodegradation causes unpredictable changes in the sensor's response characteristics (e.g. sensitivity, baseline, selectivity, etc.) and may lead to a rapid device failure. New materials would enable sensors to be deployed in the body for extended periods of time without loss of performance.

These Grand Challenges will be supported by discovery and translation of bioelectronic materials with properties specified in the roadmap, providing near-, medium- and long-term goals for the materials community.

BIOELECTRONIC MATERIALS INNOVATION IN THE UK

Materials innovation in the UK is shaped by a variety of scientific, commercial, regulatory and cultural forces. It takes many years and is expensive to certify the use of a new material for bioelectronics, dampening innovation.

A profile of the sector has been created, where observations made by stakeholders on the innovation environment have been categorised either as strengths to the UK sector or as challenges faced by it. This profile has informed this strategy's recommended actions for accelerating new materials development for bioelectronics in the UK.

UK MATERIALS FOR BIOELECTRONICS IN HEALTHCARE SECTOR

STRENGTHS

NETWORK
A collaborative and willing UK network, including regulators, the NHS, research councils, and charities.

REACH
A core group of bioelectronics and materials science research teams, with an impactful and respected research output.

COMPETITIVE
A more affordable research environment for materials innovation than other international clusters, with structures that favour innovators.

CHALLENGES

FUNDING
High development costs and long timescales for technology translation make accessing grants and investment difficult.

FACILITIES
The cost and availability of facilities needed for formulation and testing of novel materials is a barrier to innovation.

SCALING
Scale up funding is a barrier, and pathways are complex, including navigating manufacturing and regulation challenges.

DATA
Data about novel materials and their interactions with biological systems is not openly available.

SUPPLY
It is a challenge to access reliable novel materials in appropriate purities and quantities.

AWARENESS
Researchers and developers aren't identifying, understanding and meeting the needs of industry and clinicians.

DEFINITION
Bioelectronics is an emerging sector that is incredibly multidisciplinary. Its poor definition is limiting its access to funding and skills.

ACTION PLANS

A virtual centre for materials innovation in bioelectronics is needed to deliver the key actions from this strategy.

The action plans in the full report provide prioritised recommendations for those stakeholders with influence over innovation in materials for bioelectronics in healthcare, including Royce, universities and researchers, industry, the investment community, clinicians and healthcare bodies, policy and regulation bodies, funding bodies, and RTOs including Catapults.

Four key areas require immediate focus and action:

KEY AREA	REQUIREMENTS	>>> MUST DO ACTIONS
Facilities	Elevate the quality control standards and skills in existing facilities, and invest in new facilities for the standards required by this highly controlled sector.	• Ensure that the Current Good Manufacturing Practice (CGMP) standards are being met by material fabrication facilities • Upskill clean room testing, prototyping and fabrication facilities in the standards required in bioelectronics • Create a network of testing, prototyping and fabrication facilities available to those working in bioelectronics, identifying gaps in this network and establishing new facilities where needed • Direct funding at manufacturing research and innovation
Materials supply	Improve access to, and knowledge of, biocompatible materials through data standards, networking and advisory services.	• Fund research into material biocompatibility and behaviour in biological environments • Establish a standard for material biocompatibility data • Create a database or other data sharing service for material biocompatibility data • Collaborate on a catalogue of materials in use and in development for bioelectronics • Establish a UK-based biocompatible materials fabricator or supplier
Standards	Create new standards or refresh existing ones to make them suitable for bioelectronic materials, speeding up timescales and lowering development costs.	• Create digital and AI toolkits for materials computational modelling and predictive testing • Engage with Medicines and Healthcare products Regulatory Agency (MHRA) to ensure the refresh or innovations in standards meets the profiles of bioelectronic material development
Clinical focus	Promote the challenges and needs of clinicians and their industrial suppliers to those researching solutions.	• Create an industrial review process for researchers • Define unmet clinical needs that can be addressed by bioelectronic solutions and share these with innovators • Build connections between university medical school and engineering or biology researchers working in bioelectronics • Match industry challenges with relevant researchers • Attract and retain early career researchers to the UK by providing them with unique opportunities to innovate

NEXT STEPS

- **A new national hub for materials innovation in bioelectronics** should lead the delivery of these high priority actions. It would champion the sector and ultimately create a unique and globally-significant innovation capacity in the UK.
- **A Materials for Bioelectronics Challenge Programme** should be launched to coordinate the progression of the three Grand Challenges and other material properties from the roadmap.

The Henry Royce Institute was established to ensure the UK can exploit its world-leading expertise in advanced materials and accelerate innovation from discovery to application. With over £200 million of facilities in dedicated state-of-the art laboratories, Royce is ensuring that academics and industry in the UK's materials community have access to world-class research capabilities, infrastructure, expertise, and skills development.

ROYCE.AC.UK

ScotChem is the strategic alliance for the chemical sciences in Scotland. We connect industry, academic expertise, government, the third sector, and the public. We promote and support chemistry-related industries and broker strategic partnerships to address critical challenges. Our aim is to enhance research impact and translation, drive innovation and increase economic prosperity.

SCOTCHEM.AC.UK

CPI connects the dots within the innovation ecosystem to make great ideas and inventions a reality. We're a pioneering social enterprise that accelerates the development, scale-up and commercialisation of deep tech and sustainable manufacturing solutions. As a trusted partner of industry, academia, government, and the investment community, we're the catalyst that delivers sustainability and healthcare innovations to benefit people, places, and our planet.

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Urban Foresight is a multidisciplinary innovation practice dedicated to accelerating the next generation of technologies, services and policy frameworks for places. We work with ambitious organisations around the world on projects that improve lives, protect the environment and boost local economies.

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